



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OPP OFFICIAL RECORD HEALTH EFFECTS DIVISION SCIENTIFIC DATA REVIEWS **EPA SERIES 361**

MEMORANDUM

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Jelly Hendon

DATE:

24 October 2000

SUBJECT:

Occupational & Residential Human Exposure and Risk Assessment/

Characterization for Eight Fipronil Products Used Against Fire Ants and Other Pests (Chipco Banish/File Symb. 264-LIG; Chipco Choice/Reg. No.264-550; Chipco 61748A Service Fipronil/File Symb. 264-LON; H&G 61748A Fipronil Insecticide/File Symb. 264-LOL; Chipco 61748A End User Fipronil/File Symb. 264-LOE; H&G 61743A Fipronil Insecticide/File Symb LOT; Chipco 61442A Imported Fire Ant Bait; and Chipco 60818A Fipronil For Potting Soil Mixtures).

PC Code: 129121

DP Barcodes: 244048, 244049, 253656, 254050, 254074, 254314, 254320

FROM:

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Aventis Environmental Science USA LP has submitted applications for registration of the subject proposed fipronil products. All but one are granular products, the exception being a ready to use trigger pump spray product. The products and use patterns are grouped and summarized according to the following use sites: non-residential, "commercial" turf, residential lawns and turf, a ready-to-use product, and a commercial potting soil amendment. Fipronil is currently registered for use on golf courses, commercial turf, dogs and cats, field corn, rice, ant and roach bait stations, a gel bait and as a soil termiticide. The registrant has applied for registration on cotton.

SUMMARY OF USE PATTERNS AND FORMULATIONS

The following three proposed products are labeled for "commercial turf," not for domestic use (i.e., golf courses, parks, recreational areas, athletic fields and commercial turfgrass) and are intended to control fire ants, mole crickets, and nuisance ants.

Chipco Banish: 0.05% granule; applied by slit placement or broadcast; max. appl. rate 0.05 lb ai/A/application; max two applications/year with 30 day interval.

Chipco Choice: 0.1% granule; applied by slit placement or broadcast; max. appl. rate 0.05 lb ai/A/application; max. two applications/year with 30 day interval.

Chipco End User Fipronil: 0.0143% granule; applied by slit placement or broadcast; max. appl. rate 0.025 lb ai/A/application; max. two applications /year with 30 day interval; also applied to sod farms, and cemeteries. This is also proposed for use on fleas and ticks.

The following three proposed products are intended for use on residential turf.

Chipco Service Fipronil: 0.0143% granule; applied by slit placement or broadcast; max. appl. rate 0.025 lb ai/A/application with maximum two applications/year. This is also proposed for use against fleas and ticks.

H & G Fipronil Insecticide: 0.0143% granule; applied by broadcast or drop spreader; max. appl. rate 0.024 lb ai/A/application with maximum two applications/year with a minimum 90 day interval. This is proposed for use against fire ants, black ants, stinging ants, mole crickets, fleas and ticks.

Chipco Fipronil Insecticide Imported Fire Ant Bait: 0.00015% granule; applied broadcast or mound treatment; max. appl. rate 0.000023 lb ai/A.

The proposed product **H & G Ready To Use Insecticide Spray** is a liquid, in a 24 oz. trigger spray bottle intended for use as a "barrier" or "perimeter" treatment **not for use indoors.** One container will treat the equivalent of a 3000 sq. ft. house. The proposed use is against fire ants, nuisance ants, cockroaches, crickets, box elder bugs, ticks, wasps and other external residential pests.

The proposed product **Chipco Fipronil Insecticide For Potting Media Mixtures** is a 0.1% granule to be mixed with potting media to control fire ants, root weevil larvae, Japanese beetle larvae, fungus gnats, and thrips. The max. appl. rate is 0.015 lb ai/cubic yard of media.

HANDLER EXPOSURES (Occupational and Residential)

A Margin of Exposure (MOE) of 100 is adequate to ensure protection for handlers from exposures to fipronil via the dermal and inhalation routes. "Commercial" exposure estimates are based on a 70 kg body weight and residential exposure estimates are based on a 60 kg body (the later being the Agency standard for females). Fipronil is classified as a Possible Human Carcinogen. Based on the proposed label use patterns, long term (i.e., chronic) exposures are not expected nor estimated.

The subject proposed fipronil products (except the potting medium amendment which is applied one time) are applied a maximum of two times per year. As such, short term exposures are expected for residential as well as commercial handlers. Intermediate term exposures are also expected for commercial handlers.

No chemical specific data were available with which to assess potential human exposures from handling (i.e., loading/applying) or for exposure due to re-entry to a treated area. As such, the estimates of exposure are based upon the Pesticide Handler Exposure Database Version 1.1 (PHED, Surrogate Exposure Guide, August 1998), the draft "Standard Operating Procedures (SOPs) for Residential Exposure Assessments" (December, 1997) and the proposed product labels. Assumptions include the use of maximum label rates of application in every case.

PHED was designed by a task force of representatives from the U.S. EPA, Health Canada, the California Department of Pesticide Regulation and companies with membership in the American Crop Protection Association. PHED is a software system consisting of two parts—a database of measured exposure values for workers involved in the handling of pesticides under actual field conditions and a set of computer algorithms used to subset and statistically summarize the selected data. Currently, the database contains values for over 1,700 monitored individuals (i.e., replicates).

Users may select criteria to subset the PHED database to reflect the exposure scenario being evaluated. The subsetting algorithms in PHED are based on the central assumption that the magnitude of handler exposures to pesticides is primarily a function of activity (i.e., mixing, loading, or applying), formulation type (i.e., wettable powder, granule, emulsifiable concentrate), application method (i.e., aerial, groundboom), and clothing scenarios (i.e., gloves, double or single layer of clothing).

Once data for a given scenario have been selected, the data are normalized (divided) by the amount of pesticide handled resulting in standard **unit exposures** (typically in exposures to milligrams of active ingredient per pound of active ingredient handled). After normalization, the data are statistically summarized. The distribution of exposure values for each body part (chest, upper arm) is categorized as normal, lognormal, or other (i.e., neither normal or lognormal). A value of central tendency is selected from the distribution of the exposure values for each body part. These values are the arithmetic mean for normal distributions, the geometric mean for the

lognormal distributions, and the median for all "other" distributions. Once selected, the central tendency values for each body part are composited in a "best fit" exposure value representing the entire body.

The unit exposure values calculated by PHED generally range from the geometric mean to the median of the selected data set. To add consistency and quality control to the values produced from this system, the PHED Task Force has evaluated all data within the system and has developed a set of grading criteria to characterize the quality of the original study data. The assessment of data quality is based on the number of observations and the available quality control data. While data from PHED provide the best available information on handler exposures, it should be noted that some aspects of the studies included (i.e., duration, acres treated, pounds of active ingredient handled) may not accurately represent labeled uses in all cases. HED has developed a series of tables of standard unit exposure values for many occupational scenarios that can be utilized to ensure consistency in exposure assessment (Exposure Science Advisory Committee, Policy #007).

"Commercial Uses"

Estimates of exposure are presented for commercial handlers (i.e., loaders and applicators) of the three proposed commercial turf granular products. Fipronil may be applied by "slit-placement" or by broadcast application. Only broadcast application using open pour loading is presented as that method is expected to result in the higher exposure of the two methods of application.

"Fire-Ant Bait"

Estimates of exposure are presented for commercial and homeowner applications of the fire ant bait. For the homeowner use, three methods of application are assessed; hand dispersed granules, drop-type spreader, and belly-grinder broadcast. Fire ant bait mound treatment is not assessed as the exposure from mound treatment is expected to be less than the methods of application assessed.

"Home-owner Applications"

In addition to the fire ant bait formulation, an estimate of exposure is presented for the homeowner use of the proposed products used as broadcast granules on residential turf and for the Ready-To-Use trigger pump spray product.

"Plant Potting Medium Amendment"

The estimate of exposure from use as a plant potting medium amendment is presented for a highly conservative estimate of commercial use in the preparation of potting media. "Mixer" exposure is presented for open pour granule as the most conservative estimate. In this case, the mixer and applicator are the same.

HANDLER EXPOSURE TO FIPRONIL PER FORMULATION & METHOD OF APPLICATION

Job Function and Formulation	Unit Exposure ¹ mg ai/lb ai handled		Data Conf.	Units/ Day ²	AR³ lb ai/unit	ADD ⁴ derm inhal mg ai/kg bw/day		MOE ⁵ derm inhal	
0.05% G Commerc. Load open pour w gl	0.0069		med high	40 Aª	0.025 lb ai/A	9.8-5	2.8-5	>51K	>1K
Commerc. Appl Tractor drawn broadcast	0.0099 0.0012	derm ^a inhal ^a	low low	40 Aª	0.025 lb ai/A	9.9-3	2.5-5	>35K	>2K
0.00015% bait Commerc. Load open pour no gloves	0.0084 0.0017	derm ^a inhal ^a	low high	40 A ^a	0.000023 lb ai/A	1.1-7	2.6-8	>45M	>1M
Commerc. Appl Tractor drawn broadcast	0.0099 0.0012	dermª inhalª	low low	40 Aª	0.000023 lb ai/A	1.3 ⁻⁷	1.8-8	>38M	>2M
Homeowner Granular dispersed/hand	430 0.467	derm ^b inhal ^b	med med	0.5 A ^b	0.000023 lb ai/A	8.6-5	9.3-8	>58K	>500K
Homeowner Belly-grinder open pour MLA	110 0.062	derm ^b inhal ^b	med high	0.5 A ^b	0.000023 lb ai/A	2.2-5	1.24-8	>200K	>4M
Homeowner Drop Spreader open pour MLA	3.0 0.0063	derm ^b inhal ^b	low high	0.5 A ^b	0.000023 lb ai/A	5.7-7	1.2-9	>8M	>41M
Homeowner 0.0143% G Drop Spreader	3.0 0.0063	derm ^b inhal ^b	low high	0.5 A ^b	0.024 lb ai/A	6.0-4	1.3-6	>8K	>38K
Homeowner 0.05% RTU	220 2.4	derm ^b inhal ^b	med med	24 fl ^c oz/day	3.3 ⁻⁵ lb ai/fl oz	2.9-3	3.2-5	>1.7K	>1.5K
Commercial Potting Media mixt. 0.1% G	0.0069 0.0017	derm ^a inhal ^a	med high	1500 ^d yd³ med	0.015 lb ai/cu yd	2.2-3	6.4-4	>2K	78

Column Notes:

K = Thousand; M = Million

1. a. "Unit Exposures" for commercial job functions are taken from the "PHED SURROGATE EXPOSURE GUIDE - Estimates of Worker Exposure from the Pesticide Handler Exposure Database Version 1.1, August 1998, pp 16 and 30. b. Unit Exposures for homeowner applications are taken from "DRAFT Standard Operating Procedures (SOPs) for Residential Exposure Assessments," Dec. 18, 1997, pp B-3, B-4, B-5, B-6 and B-16.

- 2. a, "Units/Day" are from Science Advisory Council for Exposure Policy #9, Revised 5 July 2000;
 - b. Draft Standard Operating (SOPs) for Residential Exposure Assessments, Dec 18, 1997, p 12;
 - c. proposed label for H&G 61748A fipronil insecticide Ready To Use Spray;
 - d. Person. Comm. M Brautovich/Sun Land Garden Products to M. Christian/HED/OPP, August 2000.
- Proposed labels for Chipco Banish File Symb. 264-LIG; Chipco Choice File Symb. 264-LLN; Chipco 61748A End User Fipronil File Symb. 264-LON; H&G 61748A Fipronil Insecticide File Symb. 264-LOL; H&G 61743A
 Ready To Use Insecticide Spray File Symb. 264-LOT; Chipco 61442A Imported Fire Ant Bait; Chipco 60818A For Potting Media Mixtures.
- 4. ADD = Unit Exposure x AR x Unit/Day x 1/BW (70 kg for commercial, 60 kg for homeowner). Values = x 10^{exponent} for example 9.8 x 10⁻⁵
- 5. MOE = NOAEL/ADD (where Dermal short and intermediate NOAEL = 5.0 mg ai/kg bw/day from 21 dermal study; Inhalation short and intermediate NOAEL = 0.05 mg ai/kg bw/day from developmental neurotox. study).

An MOE of 100 is adequate to ensure protection for handlers from exposures to fipronil via the dermal and inhalation routes as used per the instructions on the proposed products. An inhalation MOE of 78 results from the extreme possibility of preparing 1,500 cubic yards of plant potting medium. For point of reference, a large dump truck may contain 20 cubic yards of material. The estimated MOE of 78 is based on open pour mixing and loading of granular material and is considered conservative. The inhalation NOAEL (0.05 mg ai/kg bw/day) is based on an oral developmental neurotoxicity study (no appropriate inhalation data were available). If 750 cubic yards of medium are prepared, the MOE would be 156. If very large volumes of plant potting media are to be prepared at one single preparation (i.e., mixing), a PF 5 dust mask should be considered as additional Personal Protective Equipment (PPE) for that task. All other MOEs are below HED's level of concern.

POST-APPLICATION EXPOSURE

Dermal post-application exposures are expected to be negligible. Fipronil is applied as a dry granule, the rates of application are very low and the granule sizes range from 297-840 microns for the 0.1% granular formulation and 840-1680 microns for the 0.0143% granular formulation. Only the 0.0143% formulations are applied to residential turf. Dermal absorption is less than 1%. Chemical-specific data are available to assess the residential post-application exposure of the proposed fire-ant uses of fipronil. The registrant has submitted a dislodgeable foliar residue (DFR) study on granular fipronil treated turf (MRID # 44506901). Data from this study suggest that fipronil cannot be dislodged from turf after a single application of granules. Therefore, post-application exposure assessments are not presented for residential turf or for golf course re-entry.

The RTU product is directed for use on the exterior walls of dwellings in 6-8" intervals, completely around the perimeter. Post-application exposure is not expected from this use pattern.

However, as points of reference relative to children, two post-application exposure estimates are presented for: 1) Post-application Potential Dose Among Toddlers from the Ingestion of Pesticide Pellets or Granules from Treated Areas (Pellets/Granules) and 2) Post-application Potential Dose Among Toddlers for Incidental Ingestion of Soil from Pesticide-Treated Residential Areas (Soil Ingestion).

HED believes that **if** a toddler were to be exposed, the exposure to the Pellet/Granule is most likely to be "episodic", that is, a one time occurrence and not likely to be repeated. It is not likely that a toddler would repeatedly locate and ingest very small, sand colored granules. Therefore the toxicological endpoint used to estimate risk in this situation is the Acute Dietary endpoint of 2.5 mg a.i./kg bw/day from an acute neurotoxicity study with the LOAEL of 7.0 mg a.i./kg bw based on decreased hind leg splay in males at 7 hours.

HED believes that incidental "soil ingestion" might occur on a repeated basis. Toddlers may ingest soil as a result of "normal" hand to mouth behavior and thus possibly ingest pesticide that has been applied to the soil. Therefore, the toxicological endpoint used to evaluate Soil Ingestion is the Short-Term Oral (1-7 days) Residential endpoint of ≤ 0.1 mg a.i./kg bw/day which is based on a rabbit developmental toxicity study where the LOAEL = ≤ 0.1 mg a.i./kg bw/day based on maternal toxicity of decreased body weight gain and decreased food efficiency. For Soil Ingestion there is an Uncertainty Factor (UF) of 3 applied for no NOAEL and UF of 100 for inter- and intraspecies variation. By design, these models are conservative estimates of oral exposure and represent worse cases of re-entry exposure.

For toddlers, the Potential Dose Rate $(PDR)^1$ (mg/day) may be calculated as: $PDR = IgR \times F \times CF1$ where

 $FDR = IgR \times F \times CFI \text{ when}$

IgR = ingestion rate of dry formulation (g/day) = 0.3 g/day

F = fraction of ai in dry formulation (unitless)

CF1 = weight unit conversion factor to convert g units in the ingestion rate value to mg for daily exposure (1000 mg/g).

Thus the PDR for the residential granule formulation = $0.3 \text{ g/day } \times 0.000143 \times 1000 \text{ mg/g} = 0.043 \text{ mg day}$.

The PDR_{norm} = the PDR/bw (15 kg for toddler) = $0.043 \div 15 = 2.8^{-3}$ mg ai/kg bw/day

MOE = NOAEL/PDR_{norm} = 2.5 mg ai/kg bw/day \div 2.8⁻³ mg ai/kg bw/day = 892. (acute oral NOAEL = 2.5 mg ai/kg bw/day) Note: 2.8^{-3} is abbreviated 2.8×10^{-3}

¹ Postapplication Potential Dose Among Toddlers from the Ingestion of Pesticide Pellets or Granules from Treated Areas in: Draft Standard Operating Procedures (SOPs) for Residential Exposure Assessments, p 19, 18 DEC 97

The Post-Application Potential Dose Among Toddlers from Incidental Ingestion of Soil from Pesticide-Treated Residential Areas* may be calculated as:

$$PDR_{1} = SR_{1} * IgR * CF_{1}$$

where PDR = Potential Dose Rate on day "t" (mg/day)

 $SR_1 = soil residue on day "t" (µg/g)$

IgR = ingestion rate of soil (mg/day)

 CF_1 = Weight unit conversion factor to convert μg of residues on soil to grams to obtain mg/day (1E-6g/ μg)

$$SR_t = AR * F * (1 - D)^t * CF2 * CF3 * CF4$$

where AR = application rate (lbs a.i./ ft^2 or lb a.i./Acre)

F = fraction of a.i. available in uppermost cm of soil (fraction/cm)

D = fraction of residue that dissipates daily (unitless)

t = post-application day on which exposure is being assessed

CF2 = weight unit conversion factor to convert the lbs a.i. in the application rate to μ g for the soil residue value (4.54E8 μ g/lb)

CF3 = area unit conversion factor to convert the surface area units (ft²) in the application rate to cm² for the SR value (1.08E-3 ft²/cm² or 2.47E-8 acre/cm² if the application rate is per acre)

CF4 = volume to weight unit conversion factor to convert the volume units (cm³) to weight units for the SR value (U.S. EPA, 1992) (0.67 cm³/g soil)

: Application Rate of 0.024 lb a.i./A ÷ 43,560 ft²/A = 5.5^{-7} lb a.i./ft²

$$SR_t = AR * F * (1 - D)^t * CF2 * CF3 * CF4$$

5.5⁻⁷ lb a.i./ft² * 1.0/cm * (1 - D)⁰ * 4.54⁸ µg/lb * 1.08⁻³ft²/cm² * 0.67 cm²/g = 0.18µg/g

PDR_t = SR_t * IgR * CF1
0.18
$$\mu$$
g/g * 100 mg/day * (1*10⁻⁶) g/ μ g = 1.8 mg day

Normalized to toddler body weight (15 kg)

$$PDR_{t-norm} = PDR_t/bw = 1.8^{-5} \text{ mg day} \div 15 \text{ kg bw} = 1.2^{-6} \text{ mg a.i./kg bw/day}$$

Margin of Exposure (MOE) = NOAEL
$$\div$$
 PDR_{norm} = 0.1 mg a.i./kg bw/day \div 1.2⁻⁶ mg a.i. kg bw/day = 83,333

^{*} From Standard Operating Procedures (SOPs) for Residential Exposure Assessments. 18 December 1997. pp 28-30.

For soil ingestion, HED's level of concern is 300. Therefore, based on conservative, screening level assumptions, the MOE for episodic ingestion of granules is 892 and the MOE for incidental soil ingestion is > 80,000, HED's levels of concern are not exceeded for toddlers as described above.

Fipronil is currently registered for use on pets. An assessment of exposures to the pet products was conducted (Memo, D246176, G. Kramer et al., 5/22/98). The probability of applying fipronil to pets and applying fipronil to control turf pests on the same day is considered to be negligible. Levels of concern were not exceeded for residential applicators or for post-application dermal exposure to toddlers. Also refer to draft memo, D236413, D. Vogel & M. Dow, 09//00. Final expected November 2000.

PHOTODEGRADATE

The fipronil photodegradate MB 46513 is not considered pertinent to this assessment. In a 26 January 1998 memorandum (EFED Section 3 Decision for fipronil on Rice Seed; D235912; Fipronil Rice Team, EBB 1 to M. Johnson, Insecticides Branch, Registration Division), EFED characterized the metabolite as follows. "Fipronil is relatively persistent and immobile in terrestrial environments." "Fipronil dissipation appears to be dependent on photodegradation in water, microbially mediated degradation and soil binding." "Since fipronil and its degradates have a moderate to high sorption affinity to soil, it is likely soil sorption will control residue movement into ground and surface waters." "Photodegradation of fipronil is a major route of degradation...in the aquatic environment.... In contrast, fipronil photodegradation on soil surfaces does not appear to be a major pathway."

Kramer et al. (memo, D246176, 5/22/98) determined that the photodegradate need not be assessed relative to the uses on pets. With the exception of the RTU product, fipronil is applied as a dry material to non-aqueous substrates, therefore it is not considered pertinent to this assessment.

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Non-Dietary Exposure Review

Subject:

Occupational and Residential Human Exposure and Risk Assesment/Characterization for 8

Fipronil Products...

Guidelines:

Other:

Exposure/Risk Assessment

DP Barcode:

D244048, D244049, D253656, D254050, D254074, D254314, D254320

MRIDs:

Chemical Codes:

129121 Fipronil

Formulation Type:

Granular, Liquid

Exposed Individual: Application Method:

Applicator, Children, Homeowner, Mixer/Loader

Belly grinder, Hand, Solid Broadcast spreader (belly grinder), Solid Broadcast spreader

(truck/tractor/ag use), Solid broadcast spreader (Scotts type - residential)

Outdoor Use Sites:

Golf Course; Non-Crop; Residential

Indoor Use Sites:

Greenhouse Use Sites:

Other Use Sites:

Airborne Techniques: Dermal Techniques:

Hand Techniques:

Foliar Techniques:

Indoor Surf. Techniques:

Reviewers:

Mark I. Dow, Dana Vogel

Review Approvers:

George Herndon Approved on:



010065

Chemical:

Fipronil

PC Code:

129121

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12000 Exposure Reviews

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